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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,609	01/26/2004	Arthur Alfaro	1230-2	8934

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EXAMINER

SEVERSON, RYAN J

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/764,609

Applicant(s)

ALFARO, ARTHUR

Examiner

Ryan Severson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 6, 9, 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of invention 1 (claims 1-14) in the reply filed on 11 January 2007 is acknowledged.
2. Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 January 2007.

Information Disclosure Statement

3. The information disclosure statement filed 26 January 2004 contains a reference that has not been considered. The reference to 5,123,715 to Amplatz is improper because 5,123,715 is a patent issued to a different inventor with different issue date than listed by applicant on the information disclosure statement. It appears applicant intended reference 6,123,715 to Amplatz. A supplemental information disclosure statement is required if 6,123,715 is indeed the reference applicant intended and would like considered.

Drawings

4. The replacement drawings were received on 01 July 2004. These drawings are accepted.

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Claim Objections

5. Claim 6 is objected to because of the following informalities: The wording of the claim is unclear. More specifically, the phrase "wherein the ingrowth enhancing material bio-compatible material" is improperly worded. Appropriate correction is required.
6. Claim 9 is objected to because of the following informalities: It appears applicant has duplicated the "Z cross-section" and the "N cross-section" in the listing of possible body shapes. Appropriate correction is required.
7. Claims 12 and 13 are objected to because of the following informalities: Both claims 12 and 13 claim a threaded valve "nab." However, claim 14 and the specification reference to the piece as a "nub." It is interpreted that applicant intended "nub" in the places "nab" has been written. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-4 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Landymore et al. (4,836,204).** Landymore et al. (hereafter Landymore) reference discloses an occlusion assembly with a collapsible body (24 and 26) that receives a radiopaque expansion medium (see column 3, lines 58-60). The expansion

of the parts (24 and 26) of the body serves to occlude an opening (see figure 1). The radiopaque dye is interpreted to be the biomarker.

9. Regarding claims 2, 8, and 9, the body has a neck (the narrow portion between parts 24 and 26, see figure 1). Both parts (24 and 26) are interpreted to be end portions. The inner surfaces of the end portions are juxtaposed with the tissue (see figure 1). The two end portions form a dumbbell shape with an H cross-section.

10. Regarding claims 3 and 4, the body is made from a compliant material, preferably latex (see column 4, lines 8-11) but can be other materials (see column 5, lines 32-35).

11. Regarding claim 10, the body further has valve (see column 3, lines 61-66).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landymore et al. (4,836,204) as applied to claim 3 above, and further in view of Marks (5,108,420).** Landymore does not disclose the assembly further has an ingrowth enhancing material such as polyurethane. Attention is drawn to Marks, which teaches a defect occlusion device may be made of polyurethane (see column 3, lines 55-57) to provide a biocompatible device that promotes ingrowth and healing and prevents fluid flow through the abnormal opening that is being treated. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the occlusion device of Landymore with polyurethane, as taught by Marks, to provide a biocompatible device that promotes ingrowth and healing and prevents fluid flow through the abnormal opening that is being treated.

15. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landymore et al. (4,836,204) as applied to claim 10 above, and further in view of Adams (6,113,609).** Landymore does not disclose an additional valve downstream from the neck of the first end portion. Attention is drawn to Adams reference, which teaches a valve (110) may be placed between the end portions (see figures 16, 18, and 20) to control the fluid passing into the distal-most end portion and retain the fluid therein independently of the other end portion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an additional valve downstream from the neck of Landymore, as taught by Adams, to control the fluid passing into the distal-most end portion and retain the fluid therein independently of the other end portion.

16. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landymore et al. (4,836,204) in view of Adams (6,113,609) as applied to claim 11 above, and further in view of Kotula et al. (5,846,261) and Konya et al.

(2002/0156499). The combination of Landymore and Adams references does not disclose the valve has a threaded nub and a retrieval device is threaded to engage the nub. Attention is drawn to Kotula et al. (hereafter Kotula) reference, which teaches a retrieval device can be threaded (see column 8, lines 57-59) and the occlusion device has a thread (see figure 28) to receive the retrieval device to allow the occlusion device to be repositioned or removed by simply screwing the retrieval device into the threaded occlusion device and then longitudinally moving the retrieval device until the occlusion device is in the desired location. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a threaded portion in the valve region and a threaded retrieval member with the occlusion assembly of Landymore and Adams, as taught by Kotula, to allow the occlusion device to be repositioned or removed by simply screwing the retrieval device into the threaded occlusion device and then longitudinally moving the retrieval device until the occlusion device is in the desired location.

17. Furthermore, the combination of Landymore with Adams and Kotula does not disclose a magnetic connection between the retrieval device and the occlusion device. Attention is drawn to Konya et al. (hereafter Konya) reference, which teaches a magnetic connection may be used between an occlusion device and the retrieval member (see paragraph 69, the portion beginning on line 1 of the top of the second

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column on page 7) to allow the retrieval device to align properly with the mating threaded portion of the occlusion device when an attempt is made to reconnect the retrieval device to the occlusion device to either reposition or remove the occlusion device.

18. **Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landymore et al. (4,836,204) in view of Adams (6,113,609), Kotula et al. (5,846,261) and Konya et al. (2002/0156499) as applied to claim 13 above, and further in view of Suon et al. (6,342,062).** The combination of Landymore with Adams, Kotula, and Konya references does not disclose the retrieval device has a grasping forceps. Attention is drawn to Suon et al. (hereafter Suon) reference, which teaches a grasping forceps may be used in a retrieval device (see figures 4-6) to allow the implanted device to be removed more easily. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the grasping forceps of Suon with the retrieval device of the combination of Landymore with Adams, Kotula, and Konya, to allow the implanted device to be removed more easily as the forceps will help align the threaded portion of the retrieval device with the threaded portion of the occlusion device.

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Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson
March 5, 2007



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

3/12/07